DEC 11 2000

510(K) SUMMARY

K001550

I. General Information

Manufacturer Name and Address:

Imatron, Inc.
389 Oyster Point Blvd.
South San Francisco, CA 94080

Contact:

J.A. Coduto
Director of Regulatory Affairs
Phone: 503-638-5500
FAX: 503-638-6328
email: jcoduto@imatron.com

Establishment Registration No.:

2936804

Common and Proprietary Names:

Common Names: CT scanner system; Computed tomography X-ray system; Scanner system; CT angiography system; CAT Scanner; Computed Axial Tomography Scanner.

Proprietary Names: EBT Ultrafast® CT scanner system; Ultrafast CT scanner system; C-100, C-150, C-150LXP or C-150XP scanner systems; C-150XP HRDS scanner systems; Electron Beam scanner system; Electron beam tomography system; Mobile Imatron scanner; Mobile electron beam tomography system; Electron beam angiography system; EBA system; EB angiography system; Mobile electron beam angiography system; Electron beam lung scanner system; Mobile electron beam lung scanning system.

Device Class:

Class II

Classification Name:

21 CFR 892.1750/Procode: 90 JAK Computed tomography x-ray system
AND 90 LLZ 892.2050

Performance Standards:	None established under Section 514 of the Food Drug and Cosmetic Act. The Imatron EBT scanner system meets the applicable requirements of the FDA Performance Standard for Ionizing Radiation Emitting Products (i.e., 21 CFR Sections 1020.30, 1020. 31, 1020. 32, and 1020.33).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2000

Mr. J. A. Coduto
Director of Regulatory Affairs
Imatron, Incorporated
389 Oyster Point Boulevard
SOUTH SAN FRANCISCO CA 94080

Re: K001550
EBT UltraFast® CT scanner system; C-100, C-150, C-150LXP or C-150XP scanner systems
Dated: September 11, 2000
Received: September 12, 2000
Regulatory Class: II
21 CFR §892.2050/Procode: 90 LLZ
21 CFR §892.1750/Procode: 90 JAK

Dear Mr. Coduto:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K001550

Device Name: EBT ULTRAFAST® CT SCANNER SYSTEM; C-100 C-150, C-150LXP; C-150XP

The Imatron Electron Beam Tomography ("EBT") Scanner system is designed and intended for use, among other cleared uses, to scan, in clinical situations requiring the acquisition of specific quantitative and qualitative information from any human anatomical cavity (including those associated with or formed by: organs, especially the heart, lungs, liver, kidneys, and colon and vessels, whether blood vessels or lymphatic system; head; chest; abdomen; pelvis; spine) whether empty or filled. Further, it is intended to function as a diagnostic x-ray system, together with pertinent software, to produce two and three dimensional images of the human anatomical cavities, using cross-sectional images reconstructed from x-ray transmission data from the same axial plane taken at different angles. This diagnostic x-ray system permits radiologic visualization during or after injection of or filling with a contrast medium or inflation with gases such as air or carbon dioxide. It also permits the viewing of data from a three dimensional volume of data from a point of view moving inside the data, including combining such views to form a so called "fly through" mode pertinent to colonographic, bronchographic, or lumenographic end points.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001550

✓

Prescription Use
(Per 21 CFR 801.109)